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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/848,781	05/03/2001	Mitchell C. Sanders	3265.1001-000	6639

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EXAMINER

SHAHNAN SHAH, KHATOL S

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 04/22/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/848,781

Applicant(s)

SANDERS, MITCHELL C.

Examiner

Khatol S Shahnan-Shah

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 December 2002 and 07 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 5-9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 10-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 13.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. Applicant's preliminary amendments, received 2/07/2003, paper # 14 is acknowledged.

Claims 1-4, 8 and 9 were amended. New claims 10-16 were added.

2. Applicant's Information Disclosure Statement, received 12/10/2002, paper # 13 is acknowledged. The references are considered by the examiner, see attached form 1449.

Election/Restrictions

3. Applicant's election with traverse of 2/07/2003, paper # 14 is acknowledged. The traversal on the ground that inventions of groups I and II are interrelated and examination of groups I and II together is requested by the applicant has been noted. This is found persuasive and therefore, groups I and II will be rejoined.

4. Claims 1-16 are pending. Claims 5-9 are withdrawn from consideration as being drawn to non-elected inventions

5. Claims 1-4 and 10-16 are under consideration.

Specification Informalities

6. The disclosure is objected to because of the following informalities:

Appropriate correction is required.

Specification page 16, line 19 the abbreviation PVDF is used, the full name or explanation of the above abbreviation is required when appears in the specification for the first time.

The use of the trademarks i.e. Novagen have been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

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Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

Drawings

7. The drawings are objected to by the Draftsperson under 37 CFR 1.84 or 1.152. See attached form PTO 948.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claim 1-4 and 10-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of detecting *Listeria monocytogenes* in sample, does not reasonably provide enablement for a method of detecting all prokaryotic microorganisms or a plurality of pathogenic microorganisms. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/or use the invention commensurate in scope with these claims.

Enablement is considered in view of the Wands factors (MPEP) 2164.01(a). Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples (6) the quantity of experimentation, (7) the relative

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skill of those in the art, and (8) the breadth of the claims.

Claim 1 recites a method of detecting the presence or absence of a prokaryotic microorganism in a sample. The scope of the claim encompass all prokaryotic microorganism. Claim 4 recites a method of detecting a plurality of pathogenic microorganisms in a sample. The scope of the claim encompass all pathogenic microorganisms including prokaryotic and eukaryotic such as pathogenic parasites, fungi, viruses, bacteria and chlamydia. The specification teaches only detection of *Listeria monocytogenes* (page 4, lines 20-25) and a FRET assay for detecting *Listeria monocytogenes* by measuring metalloprotease (mpl), which is found only in the pathogenic species of *Listeria monocytogenes* (page 8). The breadth of the claims are extremely broad, encompassing all pathogenic microorganisms. The amount of direction or guidance is limited to the isolation and detection of pathogenic species of *Listeria monocytogenes*. It is well known in the art that the detection of microorganisms is very important in particular in the food industry. It is also taught that various methods detect the presence of microorganisms in a medium of some kind to be demonstrated, consisting in taking a sample and promote the growth of the microorganism present in the sample by a suitable medium or a method. It has also been recognized in the art that although all of these media are efficacious in detecting microorganisms of specific genus, the do not, however, permit the detection of a large number of microorganisms of different genera or differentiation of pathogenic species from others (see column 1, Rambach US 5,716,799, prior art of record, applicant's 1449). While studies have shown that bacterial pathogens secrete a wide array of proteases, many of which have been extensively characterized at functional and structural levels. Although microbial proteases are now standard tools in biochemistry and cell biology, there is a

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discrepant paucity of information regarding the biological events that they may provoke in a physiological setting. Most studies deal with the problem of local substrate cleavage (see, page 3646, Vollmer et al. Infection and Immunity Vol. 64, 1996 prior art of record, applicant's 1449). Because of lack of guidance provide by the specification in regard to other pathogenic microorganisms and, in view of the lack of predictability in the art, it is determined that it would require undue experimentation by one skilled in the art to make and/or use the invention commensurate in scope with the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 2, 3, 4, 10, 13 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Kraft, G.A. (EP 0428000A1). Prior art of the record, applicant's 1449.

The claims are drawn to a method of detecting presence of a prokaryotic or a pathogenic microorganism in a sample, the method comprising the steps of:

- contacting a test sample with a substrate specific for a protease that is unique to the organism; and
- detecting cleavage of the substrate.

Kraft, G.A. teaches a method of detecting presence of a prokaryotic or a pathogenic microorganism in a sample, the method comprising the steps of:

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- contacting a test sample with a substrate specific for a protease that is unique to the organism; and
- detecting cleavage of the substrate.

see pages 2, 3 and examples 2 and 3. Kraft, G.A. also teaches measuring this activity using a quenched label. Kraft, G.A. teaches detecting the presence of pathogenic microorganism such as human immunodeficiency virus and avian myeloblastosis virus. (see page 3). The prior art anticipates the claimed method.

Since the office does not have the facilities for examining and comparing applicant's method with the method of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed method and the method of the prior art (i. e., that the method of prior art does not possess the same reagents, method steps and functional characteristics of the claimed method). See In re Best, 562 F.2 d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.


Conclusion

10. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol Shahnian-Shah whose telephone number is (703) 308-8896. The examiner can normally be reached on Monday through Friday from 7:30 AM - 4 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned to is (703) 305-3014.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

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April 15, 2002


MARK NAVARRO
PRIMARY EXAMINER